

Statement of Work

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Quality Assurance Technical Support

I. Purpose

The Environmental Protection Agency's (EPA) Office of Superfund Remediation and Technology Innovation (OSRTI) requires environmental data of known quality and of a level of quality sufficient to support decision-making and enforcement under the mandates of the Superfund Amendments and Reauthorization Act (SARA), commonly referred to as "Superfund." These environmental data are developed through analytical services performed on environmental samples taken from Superfund hazardous waste sites. The majority of analytical services are currently provided through the EPA Contract Laboratory Program (CLP), although local, State, Federal and other government agencies may also request analytical services. These analytical services submitted by other government agencies in support of the Superfund Program and the CLP are administered through the EPA by OSRTI's Analytical Services Branch (ASB). The CLP is a network of commercial laboratories working under fixed-price contracts with the EPA to perform routine sample analyses using standardized analytical methods, quality assurance/quality control (QA/QC) procedures, and data reporting formats.

The purpose of this procurement is to provide technical support that assures the development of environmental data which are of sufficient quality to meet the technical and analytical needs of OSRTI and Superfund. This contract will provide Quality Assurance Technical Support (QATS) in the following task areas:

Task I. Performance Evaluation Materials, for accurate analyte identification and quantitation.

Task II. Tape and Data Package Review, for contract compliance and technical acceptability.

Task III. On-site Audits, for inspecting facilities and equipment, and for compliance with technical contract requirements.

Task IV. Methods and Guidelines Evaluation, to assure the use of effective, up-to-date procedures.

II. General Requirements

Facilities and Equipment

The contractor shall provide adequate laboratory and office facilities as listed in this Statement of Work (SOW), (see V. Facilities and Equipment). **Equipment and software shall be provided by the contractor.** The contractor shall provide from its own inventory and not as a direct charge, any additional general purpose equipment, furniture and supplies required for performing all administrative and operational functions of the contract, including, but not limited to personal computers and computer software. Any equipment for administrative purposes is considered general purpose and will not be supplied by the Government either as additional Government Furnished Equipment or as Contractor

Acquired Property. However, acquisition for equipment for new technologies may be provided if EPA deem necessary.

Personnel

The contractor shall provide qualified professional, technical/scientific personnel as necessary for contract performance (see the anticipated labor and skill classification definitions included as Attachment K).

Tasks

The contractor shall perform work in the Task areas described in the SOW (see IV. Task Descriptions) as ordered through EPA-issued Task Orders (TOs), as described in the Contract Schedule, and in accordance with any written technical direction provided by the EPA Project Officer (PO) or Task Order Manager (TOM) (See Clause H.18).

In order too successfully complete work under certain Task areas, the contractor shall perform qualitative and quantitative analysis of organic chemical compounds employing gas chromatography/electron capture detector (GC/ECD), GC/flame ionization detector (FID), GC/mass spectrometer (MS), high performance liquid chromatography (HPLC), and other organic analytical techniques, as specified by Task Order. The contractor shall perform qualitative and quantitative analysis of inorganic chemical compounds employing inductively coupled plasma (ICP) emission spectroscopy; flame, flameless and cold vapor atomic absorption (AA) spectroscopy; ICP-MS; ion trap spectrometer-40; and other inorganic analytical techniques, as specified by TO. The contractor shall perform qualitative and quantitative analysis of tetra through octa dioxins and furans employing selected ion monitoring (SIM) GC/MS and other techniques, as specified by TO. The contractor shall perform qualitative and quantitative analyses to characterize samples which can include chemical, physical, biological, and ecological parameters. The contractor shall perform the above analyses on the following media: air; liquids (aqueous, organic, multiphase); soils; solids; sediments; biological tissues; and other media, as specified by TO.

The analytical methods used by the contractor may vary from those needed to perform qualitative screening, to state-of-the-art quantitative methods that are needed to obtain well-documented data of known quality for regulatory, enforcement, or legal purposes. The contractor shall perform these methods over a wide range of concentrations (percent to parts per trillion) in an environment free of interfering background/laboratory contamination.

Quality Assurance (QA)

The contractor shall at a minimum adhere to the EPA-approved Quality requirements for solicitations and contracts during the solicitation. The quality system documentation shall meet at a minimum the requirements outlined in American National Standard, “*Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*” (ANSI/ASQC E4). The quality system documentation will be modified as needed during contract performance. Contractor Work Plans prepared in response to EPA-issued TOs shall include a discussion of the quality assurance procedures and applications necessary for carrying out the TO task. Quality assurance project plans for individual work activities within the TO task may also be required. EPA quality assurance policies and standard operating procedures are described in “U.S. EPA Requirements for Preparing Quality Management Plans” (QA/R-2) and ANSI/ASQC E4.

Standard Operating Procedures

The contractor shall write and implement a complete set of standard operating procedures (SOPs) which include, but are not limited to: standard traceability; sample receipt, log-in, storage and security; chain of custody; instrument logbooks; prevention of cross-contamination; QA/QC guidelines; and good laboratory practices (GLP). The contractor shall submit these SOPs within 30 days following contract award for review and approval. All SOPs developed under, or used for this contract becomes the property of the EPA and must be approved by the Agency before implementation.

Chain-of-Custody

Chain-of-custody procedures must be maintained for all samples. Chain-of-custody records are the property of the EPA.

Record Keeping

The contractor shall be certified by International Organization Standardization (e.g., ISO-9001 or equivalent). Certification is required to add a high level of quality documentation essential for achieving and maintaining the highest quality in standard industry practices. Bound, serially numbered laboratory notebooks must be used to record data and observations made during laboratory studies and site visits, and at all other times during performance of contract tasks. All analyses and studies must be documented, as specified by TOs, to include: identification of assumptions and clear explanations of their validity and limitations; calculations, supported by sufficient data and explanation to permit cross-checking; raw data for projects, documented in a manner that can be easily interpreted by a technical person, to facilitate review and/or completion by alternate technical persons; and, clearly presented investigative procedures. Maintenance and run logbooks for all major equipment recording analysis of all standards and samples shall be maintained. The laboratory notebooks and instrument logbooks remain the property of the EPA at the termination of this contract. The contractor shall not release any information gathered as a result of this contract to anyone other than the EPA PO or TOM for a specific TO, unless prior written approval has been granted by the EPA PO and Contracting Officer (CO).

Health and Safety

The contractor shall provide for the health and safety of its employees during contract performance, whether such performance is at a government or contractor-controlled facility. The contractor must ensure that appropriate safety precautions are observed and that personnel involved in the sampling, analysis and characterization of actual or simulated toxic and hazardous waste materials will not be endangered. To help ensure worker safety, the contractor shall comply with provisions of the Occupational Safety and Health Administration (OSHA) standard, "Occupational Exposure to Hazardous Chemicals in Laboratories," which includes a provision for the development of a Chemical Hygiene Plan. This standard appears in Title 29 of the Code of Federal Regulations (CFR) Part 1910.1450, and may be obtained from the U.S. Government Printing Office. The contractor must assume full responsibility and all risk for the safety of its employees.

Material Handling/Disposal

The contractor must ensure that samples, standards and reference materials shipped from its laboratory facility are shipped safely and within the required time schedule specified in government-issued TOs. The contractor must comply with all relevant Department of Transportation, Resource Conservation and Recovery Act (RCRA), Toxic Substances Control Act (TSCA), OSHA and other regulations governing the handling, shipment and disposal of hazardous waste/materials. Failure to follow all Federal regulations may be grounds for terminating the contract for default. This includes the packaging and labeling of the samples and sample containers, and obtaining the required permits and documentation for their shipment.

The contractor must safely store and dispose of all materials handled or generated under this contract, including excess samples of the wastes being studied. Disposal shall be at approved disposal facilities and done in compliance with all applicable Federal (e.g., CERCLA/SARA, RCRA, TSCA), State and local regulations. Shipment shall be in compliance with all Federal, State and local regulations. Other special shipment and disposal requirements shall be specified in TOs.

Interaction

The contractor shall be required to interact (e.g., coordinate Performance Evaluation Material (PEM) shipment or transmit information) with various EPA programs and contract organizations, such as, but not limited to: contractors providing sample and data management, administrative, and technical support to ASB; the Office of the Inspector General performs audits, evaluations, and investigations of EPA and its contractors, to promote economy and efficiency, and to prevent and detect fraud, waste, and abuse. Contractor interaction with these and other Agency groups shall be determined by the EPA PO or CO. Such interaction is for the purpose of communicating information or coordinating activities only, and does not include the provision of direction or the receiving of direction to or from other EPA offices or contractors.

III. Program Structure

The EPA PO, located in the Office of Superfund Remediation and Technology Innovation in Washington, D.C., will monitor contractor technical performance. All work shall be ordered through TOs issued by the CO to the contractor.

The contractor shall designate a Program Manager located on-site at the contractor's laboratory facility. The Program Manager shall be responsible for the performance of work in accordance with the terms of EPA-issued TOs. The Program Manager shall provide information on the status and progress of activities to the PO as required by the contract TO and submit Work Plans and other contract-required status and financial reports to the CO and PO, as required by the terms of the contract.

The Program Manager shall notify the PO regarding any problems encountered in the performance of work that will affect work quality or schedule and shall implement PO written direction in the resolution of problems. The Program Manager shall not deviate or approve deviation from an approved Work Plan without prior written approval from the EPA CO, or from a TOM without prior written approval from the EPA CO.

The Program Manager shall be responsible for maintaining technical and financial integrity in performance of assigned activities in accordance with EPA-issued TOs, and contract terms and conditions. The Program Manager must monitor each TO and ensure that all Task activities are conducted within the scope, budget and schedule specified in the EPA-approved Contractor Work Plan and in accordance with EPA issued TOs, the scope of work of the contract, and the established costs of the contract.

IV. Task Descriptions

The EPA may order work within any of the following task areas at any time during the contract period of performance.

Task I. Performance Evaluation Materials

1. The contractor shall develop, test, produce and ship organic and inorganic reference materials including, but not limited to, Performance Evaluation Samples (PESs) and Quarterly Blind (QB) samples, in accordance with TOs. The contractor shall obtain PEMs from authorized commercial sources as directed by the EPA PO or TOM.
2. The contractor shall characterize/develop, test, produce and ship real-world matrices from environmental or synthetic sources to be used as reference materials (RMs). Synthetic samples are to be used if relevant environmental samples are not available. Prior to the production of PES and reference materials, the contractor must communicate with the EPA TOM to obtain instructions and formulas.
3. The contractor shall develop and maintain an inventory of multi-matrix, multi-analyte, multi-level PEMs and RMs. The contractor shall respond to orders for the delivery of such materials in accordance with TOs and develop a system to facilitate and track the inventory, orders and distribution of these materials. Any remaining PEMs and RMs from the existing repository at the end of the current contract will be transferred to the new contract.
4. The contractor shall perform referee analyses of QA/QC RMs and PEMs. These referee analyses shall be performed in accordance with designated CLP protocols, applicable equivalent protocols (i.e., Statements of Work from relevant Superfund contracts), or other analytical methods approved for use under the Superfund Program, unless otherwise specified by the TO. The analyses will be used in a quality assurance function to verify analyte presence and concentration.
5. The contractor shall score Performance Evaluation/QB samples using SOPs for organic and inorganic scoring provided by EPA, or developed by the contractor and approved by EPA.
6. The contractor shall provide technical support in developing new, or modifying existing algorithms for scoring RMs and PEMs.
7. The contractor shall be responsible for support in the development and update of SOPs to be applied internally in its development, use and handling of PES and RMs, based on guidelines and materials provided by the Agency. These shall include, but not be limited to SOPs for standard

traceability, sample receipt, log-in, storage and security, chain-of-custody, instrument logbooks, prevention of cross-contamination, and good laboratory practices.

8. The contractor shall provide technical support in the development of QA/QC guidelines to be applied in the development, use and handling of PEMs and RMs.
9. The contractor shall maintain an organized compilation of PEM and RM evaluation data for the purposes of trend analyses for monitoring performance of laboratories, summarization and report preparation. All evaluation data are to be delivered at the end of the contract period in a format to be determined by the EPA PO or TOM.
10. The contractor shall maintain proper chain-of-custody on all RMs and PEMs which shall include, but not be limited to, the requirement that RMs and PEMs be held in a secure room with restricted access.
11. The contractor shall develop and maintain procedures to assure the quality and integrity of PEMs and RMs that includes, but is not limited to, proper storage conditions.

Task II. Tape and Data Package Review

Periodic, in-depth audits are conducted on the contract-required hard copy, electronic and magnetic tape deliverables submitted by CLP and Superfund contractors. The purpose of these audits is:

1. To identify contractual technical/reporting deficiencies with the deliverables provided by CLP/ Superfund contractors;
2. To identify weaknesses in the present CLP SOW technical/reporting requirements and provide recommendations to ASB on how to correct/improve CLP SOW requirements;
3. To monitor for contractual non-conformances which may indicate potential fraudulent activity by a CLP or Superfund contractor.

During the audit, an item-by-item review is conducted, which cross-compares the information reported on the hard copy, electronic and magnetic tape (if applicable) deliverables. Examples of items to be checked are: instrument parameters/wavelengths, integration/quantitation procedures, calculations, accuracy of analyte identification, recoveries, analytical sequence requirements, detection limits, standard concentrations used, flagging of results, chromatography, calibrations, readability/completeness of tapes and adherence to quality control requirements. The specific subtasks to be performed in data tape/data package review are as follows:

1. The contractor shall review data packages from all analytical services (to include, but not be limited to organics, inorganics and dioxin) for contract reporting completeness and technical compliance using SOPs for data package review provided by the EPA, or developed by the contractor and approved by EPA. Data to be reviewed includes State, local, and other government agencies' CLP Routine Analytical Services (RAS) data, CLP Non-Routine Analytical Services (NRAS), field analytical data and analytical data generated to support Superfund activities, as specified by TOs.

2. The contractor shall review organic and inorganic data tapes (e.g., pesticide and mass spectrometry data tapes or computer diskettes) from CLP Laboratories and other laboratories which supply analytical data via electronic media to support Superfund activities or in support of local, State or other government agencies, as specified by TOs. Data tapes shall be reviewed for good laboratory practices and contract compliance using SOPs provided by the EPA or developed by the contractor and approved by EPA. Specific items to be assessed shall include, but not be limited to: electronic media for tape readability, file structure and content; tuning (MS performance); initial calibration; continuing calibration; user-generated libraries; sample identification and quantitation; method blank; and chromatography.
3. The contractor shall provide technical support in the development of SOPs for tape and data package reviews, based on guidelines and materials provided by the Agency.
4. The contractor shall develop and/or maintain an organized compilation of tape and data package review information for the purposes of trend analyses for monitoring performance of laboratories, summarization and report preparation.
5. The contractor shall maintain proper chain of custody on all data packages and tapes which shall include, but not be limited to, the requirement that data packages and tapes be held in a secure room with restricted access.

Task III. On-site Audits

1. The contractor shall provide technical support to the Agency in performing pre-award and post-award (routine and special) onsite audits of analytical laboratories for compliance with contract requirements. These audits shall be limited to CLP laboratories and other laboratories which supply data to support Superfund activities, as specified by TOs. These activities shall be limited to audits identified by EPA in writing and must be performed in accordance with SOPs provided by the EPA, or developed by the contractor and approved by EPA. During such activities, the contractor shall at all times be in the presence of an EPA official (i.e., either the PO, CO, or TOM) who is involved in the conduct of the audit. Contractor personnel shall be identified as contractors, which includes the wearing of identification badges. The contractor shall use an Agency-approved checklist to record observations during the audit, and shall refer contractual questions to EPA personnel involved in the audit. The contractor shall not provide any specific direction or recommendation to the auditee.
2. The contractor shall prepare schedules and information packages as specified by TOs, to be used for on-site audits by EPA audit teams. Schedule development is based on data reviews, tape reviews, Regional reviews, contract compliance screening (CCS) reports, exception/trend reports, QB performance and/or special requests from EPA officials. Information packages are based on data submitted by the analytical laboratory to be visited. Each report should identify problems with the submitted data, recommend potential corrective actions and be prepared in accordance with format and reporting criteria provided by the EPA.
3. The contractor shall provide technical support in the review of SOPs of CLP and other laboratories which supply analytical data to support Superfund activities that are subject to the

on-site audits. This review shall be based upon objective audit criteria only, from guidance and materials provided by the Agency as stipulated in individual TOs.

4. The contractor shall provide technical support in the development of QA/QC guidelines to be applied in its performance of on-site audits.
5. The contractor shall develop and maintain an organized compilation of on-site audit data and information for the purposes of trend analyses for monitoring performance of CLP and non-CLP laboratories, summarization and report preparation.
6. The contractor shall prepare program reports on-site audits. Standardized checklists provided or approved by the Agency must be used to record observations made during laboratory studies and site visits. Summary reports on site visits shall be clear, concise and timely, and in accordance with format and reporting criteria provided by the Agency by specific TO(s).

Task IV. Methods and Guidelines Evaluation

The Analytical Services Branch (ASB) is responsible for providing analytical methods for use in the Superfund program. Also, ASB, in conjunction with the Superfund Quality Assurance Officer, is responsible for establishing appropriate QA/QC procedures to be incorporated into Superfund analytical methods. The main functions under this task are:

1. Developing new analytical procedures/methods for use in the Superfund Program, and comparing field and laboratory analytical methods;
2. Updating, modifying and/or evaluating EPA methods, other Federal agency methods, State methods, or methods published in commercial or scientific literature for use in the Superfund program;
3. Testing and evaluating new equipment, instruments and/or techniques for use in Superfund analytical methods;
4. Designing and conducting experiments to evaluate and document new and current Superfund method performance; and
5. Designing, testing and evaluating appropriate QA/QC procedures to be incorporated into the Superfund analytical methods.

The specific subtasks in conducting method development are as follows:

1. The contractor shall develop and evaluate all aspects of field and laboratory analytical methods. This involves conducting single and multi-laboratory studies to support methods' development and validation. Method aspects to be included are: preservation of samples; holding times; sample preparation; sample analysis; result reporting; and the associated QA/QC. The evaluation shall include: a determination of the probable concentration ranges of analytes of interest and interferences occurring in real-world samples that will be analyzed by the method; an assessment of the clarity, efficiency and accuracy of the methods and protocols; and, laboratory

and field tests of new methods. In addition, the contractor shall recommend data documentation based on existing EPA documentation requirements. For existing new or unvalidated methods, such as field and screening methods, the contractor shall research and evaluate the methods to ensure that equipment, supplies, techniques and procedures cited are accurate, that the methods would provide effective performance and that identified QC parameters and criteria are accurate and achievable. Where deficiencies are found, the contractor shall identify and recommend improvements. The contractor shall also develop protocols for the evaluation of methods according to Agency-defined requirements. Evaluation criteria for methods, including detection limit requirements, accuracy, precision, and other parameters will be provided by the Agency in specific TOs.

2. The contractor, as specified by TO, shall statistically evaluate data and conduct studies for data assessment and methods' development, monitoring and improvement. The contractor may be required to develop optimal experimental designs and to analyze and interpret study data (e.g., variance components, test power for statistical inferences).
3. The contractor shall investigate the use of new instruments (may be provided by EPA if required) and analytical techniques through their application in CLP or other analytical protocols in the analyses of samples, PEMs, or RMs, as specified by TO. The contractor also shall evaluate and demonstrate the applicability of instruments and techniques that are not classified as new, but are not routinely applied to sample analysis, as specified by TO, as well as expand and improve environmental applications of instruments and techniques routinely used for sample analysis.

Task V. Logistical and Administrative Support

1. The contractor shall provide technical instruction courses on subjects to include, but not be limited to: QA/QC procedures; conducting on-site laboratory evaluations; audits on data generated by analytic instruments such as ICP-MS data audits; and the use of performance evaluation materials, as directed by EPA TO. The contractor will be required to prepare the curricula and to prepare course materials including manuals, handouts, slides, and audio/video tapes. The contractor also shall conduct the courses which may be required at remote locations as designated in TOs. All materials and lectures shall be pre-approved by EPA before presentation.
2. The contractor shall provide expert witness testimony in support of the information gathered or duties performed under this contract, including, but not limited to data packages and data electronic media which the contractor has audited. Such witness services may be required before hearings, boards, or in judicial proceedings.
3. The contractor shall maintain records and files generated or utilized in support of tasks under this contract SOW, as directed by EPA, to include hard copy and electronic data files and organic and inorganic tape files. Data from audited cases, data on electronic media, such as GC/MS and ICP/MS magnetic tapes, pesticide GC/ECD computer diskettes, inorganic tape and computer diskette audits, tapes involved with Inspector General (IG) investigations, all are considered to be records and therefore subject to the laws and disposition schedules of the Federal Government. Following required retention periods, data shall be purged or transferred to the Federal Records Center (FRC), as directed by EPA. The TOM will be notified before the

disposal of any IG tapes. The PO shall be provided with a list of all purged data and data transferred to the FRC.

V. Specified Facilities and Equipment Requirements

The contractor shall provide office facilities sufficient to support the administrative functions required under the contract. These facilities shall include a conference room suitable for meetings between EPA and contract personnel.

The contractor shall provide an analytical laboratory facility suitable for the performance of chemical analyses ranging from trace analyses to percent levels for organic compounds and inorganic constituents. Analyses are conducted to characterize samples regarding chemical, physical, biological, and/or ecological parameters. The storage, handling and disposal of materials that can present chemical, physical, and/or biological hazards require that the facility design conform to all applicable Federal (e.g., OSHA, EPA, DOT), State and local regulations. Developed in accordance with applicable safety and health design requirements, the contractor laboratory facility shall have the following:

- adequate sample receipt/storage areas;
- wet chemistry/sample preparation areas equipped with appropriate hoods;
- sufficient utilities for the installation and operation of all analytical instruments and equipment listed as Government Furnished Property;
- sufficient instrument laboratory space to segregate: volatile organic analyses; semi-volatile analyses; inorganic analyses; high concentration sample preparation and analyses; and, low-level drinking water-type analyses;
- area(s) designed for: the safe handling of high concentrations of hazardous materials (including pure toxic chemicals; the preparation of field samples collected from hazardous waste sites; handling/preparation of dioxin and other highly hazardous performance evaluation materials; and providing an environment that will not contaminate the remainder of the laboratory or the surrounding environment.